Customer No.

Attorney Docket No. 7414.0059

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DO NOT ENT In re Application of:

OK TO ENTER RUSSEll HIGUCHI

Group Art Unit: 1743

OK AS EN Polication No.: 08/968,208

Examiner: Snay, J.

CPA Filed: November 20, 2000

> Attention: Box AF **Expedited Procedure After Final**

INSTRUMENT FOR MONITORING For:

NUCLEIC ACID AMPLIFICATION

Box AF

Assistant Commissioner for Patents Washington, DC 20231

Sir:

RESPONSE AFTER FINAL

Applicant responds to the final Office Action mailed November 6, 2002 (Final Action). Claims 30, 31, 35 to 40, and 44 to 47 are pending and under consideration.

The Examiner stated that claims 39, 40, and 44 to 47 are allowed.

The Examiner rejected claims 30, 31, and 35 to 38 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Final Action at page 2, Item 2. The Examiner cited the Office Action mailed May 22, 2002 (Paper No. 41), for the reasons for the rejection.

In Paper No. 41, the Examiner contended that "the system is operable to detect a signal while the reaction vessel is in a sealed condition, which is clearly dependent upon the particular reaction vessel." Paper No. 41 at page 5. The Examiner then contended that the claim is of indeterminate scope unless the reaction vessel is recited as a structural element of the claim. Id.

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In response, applicant had pointed out that a claim reciting "a microscope comprising: a platform adapted to receive a microscope slide, and a light source operable to emit light through the microscope slide" would not be indefinite if it did not positively recite the microscope slide as a structural element. In the Final Action, the Examiner disagreed. Final Action at page 2.

The Examiner further contended that the specification could be used to evaluate a claim term that is positively recited as a claim element, but could not be used to evaluate a claim term that is not positively recited as a claim element. *Id.* The Examiner stated that no structure can be attributed to the vessel if it is not positively recited as a claim element. *Id.* The Examiner further stated that "claim 30, by its recitation of a thermal cycler 'adapted to receive, at least on[e] reaction vessel' and a detector operable to detect a fluorescence optical signal 'without opening the at least one reaction vessel', is indefinite because the noted language defines structural language upon a term which cannot itself be ascribed any structural definition." *Id.*

Applicant respectfully traverses the rejection.

To maintain a rejection based on indefiniteness under § 112, second paragraph, the Examiner must establish that one skilled in the art would not understand what is encompassed by the claim. Addressing the proper inquiry for definiteness, the M.P.E.P recites:

Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

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M.P.E.P § 2173.02, page 2100-194, column 2.

The Examiner cites no authority for his position that the analysis of definiteness of claim language varies depending upon whether the claim language in question is a positively recited element of an apparatus or is not a positively recited element of an apparatus. The M.P.E.P clearly discusses the proper analysis for *claim language*, and does not exclude from that analysis claim language that is not a positively recited element of a claimed apparatus. Simply because claim language is not a positively recited structural element of a claimed apparatus does not mean that such claim language is analyzed in a vacuum.

Apparatus claims may define elements in view of their interaction with components that are not positively recited as elements of the apparatus. Applicant had previously provided the analogy of the microscope. Applicant respectfully disagrees with the Examiner's position that such a claim to a microscope would be indefinite without reciting the microscope slide as a positive element of the microscope.

The U.S. Patent and Trademark Office has repeatedly issued apparatus claims that define elements in view of their interaction with components that are not positively recited as an element of the apparatus. Providing evidence of that fact, applicant encloses six exemplary U.S. patents that contain such claims.

For example, claim 1 of U.S. Patent No. 6,448,066 B1 (the '066 patent) recites a rotary thermocycling apparatus that comprises:

- (a) a plurality of stations for receiving samples in a flat-bottom container . . . ;
- (b) means to move each said flat-bottomed container from one station to another station in predetermined sequence;

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- (c) at least two of said stations having a heating unit **adapted to be lowered over a container** located on said station, each heating unit being comprised of a section with a flat lower surface **that is adapted to be lowered into said container** close to but not in contact with the sample in the container; and
- (d) a least one station . . . having a spray unit adapted to spray a liquid reagent(s) into a container located at said one station.

(Emphasis added.)

Moreover, claim 3 of the '066 patent recites

The apparatus of claim 1 in which said station of (d) is adapted for removal of a cover plate from a container located on said station prior to activation of the spray, and for replacement of the cover plate after said spray has terminated.

(Emphasis added.)

Thus, claims of the '066 patent include positively recited elements of the apparatus that are defined by their interaction with a container that is not positively recited as an element of the apparatus.

As another example, claim 1 of U.S. Patent No. 6,489,172 B1 (the '172 patent) recites a fluid specimen sampling device comprising:

an expressor having a distal opening and *adapted to receive an absorbent member* having a fluid absorbed therein;

means . . . for compressing the absorbent member as the absorbent member is passed into the expresser to effect expression of at least a portion of the fluid from the absorbent member; and

collection means . . . for collecting the portion of fluid expressed from the absorbent member

(Emphasis added.)

Thus, claim 1 of the '172 patent includes positively recited elements of the device that are defined by their interaction with an absorbent member that is not positively

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recited as an element of the device. (Claim 15 of the '172 patent depends from claim 1 and positively recites the absorbent member as a positive claim element of the device.)

In addition, applicant has highlighted pertinent claim language on the enclosed copies of the other four patents (U.S. Patent Nos. 5,870,222; 6,488,342 B1; 6,484,433 B1; and 6,488,420 B1).

In conclusion, applicant asserts that the scope of the presently rejected claims is clear without positively reciting the vessel as an element of the apparatus. Thus, applicant respectfully requests reconsideration and withdrawal of the § 112, second paragraph, rejection.

Applicant respectfully asserts that the application is in condition for allowance and requests issuance of a Notice of Allowance. If the Examiner does not consider the application to be in condition for allowance, applicant requests that he call the undersigned at (650) 849-6620 to set up an interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: January 16, 2003

M. Paul Barker

Reg. No. 32,013

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP